

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Peter HIMMELSBACH et al.

Confirmation No. 5165

Group Art Unit: 1794

Serial No. : 09/601,029

Examiner: Piziali, Andrew T

Filed : July 26, 2000

For : SUPPORTING MATERIAL FOR MEDICINAL PURPOSES

REPLY BRIEF UNDER 37 C.F.R. § 41.41(a)(1)

Commissioner for Patents
U.S. Patent and Trademark Office
Customer Service Window, Mail Stop Appeal Brief - Patents
Randolph Building
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Alexandria, VA 22314

Sir:

This Reply Brief is in response to the Examiner's Answer mailed April 21, 2008, the period for reply extending until June 23, 2008 (June 21, 2008 being a Saturday).

In the Examiner's Answer, the grounds of rejection set forth in the final rejection are maintained. Appellants note that the Examiner's Answer does not sufficiently address several of Appellants' arguments as to why the rejections are without merit, and misrepresents some of the facts. These deficiencies have prompted the present Reply Brief.

Appellants also note that this Reply Brief is being filed under 37 C.F.R. § 41.41(a)(1) and is directed to the arguments presented in the Examiner's Answer, and therefore must be entered unless the final rejection is withdrawn in response to the instant Reply Brief.

In order to avoid repetition, the following response to the Examiner's arguments in the Examiner's Answer will be limited to issues which in Appellants' opinion are important enough to warrant a further comment. Accordingly, Appellants' silence with respect to any allegations set forth in the Examiner's Answer which are not specifically addressed below should by no means be construed as Appellants' admission that these allegations are of any merit.

REPLY

1. Regarding the rejection of claims 37-43, 45-52 and 55-65 under 35 U.S.C. § 103(a) as allegedly being unpatentable over Merkle et al., U.S. Patent No. 5,527,536 (hereafter "MERKLE") in view of Lucast et al. U.S. Patent No. 6,479,073 (hereafter "LUCAST I") in view of Koketsu et al., U.S. Patent No. 5,547,223 (hereafter "KOKETSU"), the Examiner appears to maintain the position that one of ordinary skill in the art would have been motivated to replace the polymeric film used as backing layer in the active ingredient patch of MERKLE by an overstitched nonwoven mentioned in LUCAS I, despite the fact that the numerous examples of MERKLE employ exclusively a polymeric (polyester) film as backing layer, that LUCAST I mentions an overstitched nonwoven as only one of many examples of backing layers that can be used and none of the 81 exemplary articles of LUCAST I comprises an overstitched nonwoven as the backing layer and that, consistent with the teaching of MERKLE, most of the exemplary articles of LUCAST I comprise polymeric (polyester and polyurethane) films as backing layer.

The only reason for maintaining this position is given by the Examiner at page 22 of the Examiner's Answer where it essentially is alleged that because LUCAST I discloses

that an overstitched nonwoven is a viable backing layer one of ordinary skill in the art would have replaced the polymeric film backing layer of MERKLE by an overstitched nonwoven.

The Examiner's reliance on *KSR v. Teleflex* at the bottom of page 22 of the Examiner's Answer is noted. In this regard, Appellants point out that this decision states that often, it will be necessary to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. This analysis should be made explicit. There must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness. *KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1740-1741. "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs one to look with care at a patent application that claims as innovation the combination of two known devices according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does." *Id.*, at 1741, emphases added.

Appellants point out that all that the Examiner alleges is that overstitched nonwovens were known for use as backing material from LUCAST I, without providing any explanation whatsoever as to why this would have been an apparent reason for one of ordinary skill in the art to replace the polymeric (polyester) film of MERKLE by an overstitched nonwoven.

2. At page 23, first paragraph, of the Examiner's Answer the Examiner states (bold face and underlining added):

The appellant asserts that one skilled in the art would be "discouraged" to use a nonwoven instead of a film because there would be a "substantially higher risk" that the **adhesive** would "evaporate through and/or ooze out of the backing material." The Examiner respectfully disagrees. Firstly, the applicant has failed to show, or attempt [*sic*] to show, that the **adhesive** would necessarily evaporate through and/or flow through the nonwoven material. It is well established that unsupported arguments are no substitute for objective evidence. Secondly, Merkle discloses that "Preferably, the...adhesive composition is applied onto the removable protective layer...and covered with the backing layer." (see the paragraph bridging columns 4 and 5) Clearly the **adhesive** would not flow through the nonwoven backing layer because it is adhered to the protective layer. Thirdly, the applicant has failed to show, or attempt [*sic*] to show, how the alleged partial "oozing" would destroy the invention of Merkle.

In contrast to the above allegations, the passage of the Appeal Brief to which the Examiner appears to refer states (underlining in original, bold face added):

There is at least one reason why one of ordinary skill in the art would even be discouraged to use any nonwoven as replacement for the polyester film backing material of MERKLE: According to MERKLE, the **active substance** that is to be incorporated into the pressure-sensitive adhesive is a substance which, at the temperature at which the adhesive bonds, is a readily volatile liquid (see, e.g., Abstract of MERKLE). It is apparent to one of ordinary skill in the art that when using a (relatively porous) nonwoven instead of a (relatively dense) polyester film as backing material for the self-adhesive matrix of MERKLE there is a substantially higher risk for the **active substance** to evaporate through and/or ooze out of the backing material during use and/or storage of the laminate. (This is likely also the reason why the removable protective layer of the laminate of MERKLE is a polyester film as well.)

Accordingly, the Examiner apparently has misread/misunderstood Appellants' arguments. At any rate, it is not seen that Appellants need to provide evidence that the active substance of MERKLE would necessarily have evaporated through and/or oozed out of an overstitched nonwoven if an overstitched nonwoven had been used as backing material instead of the polyester film of MERKLE. There can be no doubt in Appellants' opinion that it can reasonably and objectively be expected that a substance which is characterized as a

readily volatile liquid will evaporate to at least some degree through a porous material such as a nonwoven. At any rate, even if in actual practice this expected evaporation/oozing would in fact not occur, this does not change the fact that in view of the reasonable expectation that it would occur, one of ordinary skill in the art would not be motivated to even try using a nonwoven as a backing material in combination with a readily volatile liquid (the active substance of MERKLE).

Also, it is unquestionable in Appellants' opinion that even if partial evaporation/oozing of the active substance may not necessarily be considered to "destroy" the invention of MERKLE in the sense that it would make the patch completely useless, it is apparent that loss of active substance is a significant disadvantage both from an economic (active substances are usually quite costly) and a therapeutic point of view (administration of a smaller amount of active substance by the patch than intended and expected).

3. With respect to the comments in the last paragraph of page 23 and page 24 of the Examiner's Answer regarding the alleged motivation to combine the teaching of KOKETSU with those of MERKLE and LUCAS I, Appellants respectfully maintain their position that one of ordinary skill in the art who wants to increase the strength of an overstitched nonwoven for use as a backing material in a medical patch would not expect to find any useful suggestions in this regard in a document which relates to a webbing (i.e., the opposite of a nonwoven) for restraining a vehicle occupant (e.g., a safety belt).

It further is pointed out again that the solution to this problem disclosed in KOKETSU (increasing the number and length of stitch rows and the number of stitches in

relation to the length of the stitch rows) is different from, and fails to suggest, using a number of stitches of at least 3/cm of web as recited in, e.g., present independent claim 37.

4. With respect to the Examiner's comments at pages 25 and page 26, first two paragraphs of the Examiner's Answer regarding the rejection of claims 63-73, 75-82 and 85-95 under 35 U.S.C. § 103(a) over MERKLE in view of LUCAST I in view of KOKETSU in view of Wildeman et al., U.S. Patent No. 3,967,472 (hereafter "WILDEMAN"), Appellants submit that the Examiner's allegations are clearly based on hindsight.

For example, the Examiner essentially alleges that one of ordinary skill in the art who (for any unknown reason) wants to modify one particular aspect of the medical patch of MERKLE, i.e., the backing layer, would do so based not only on the teaching of LUCAST I (which discloses overstitched nonwovens as one of many examples of backing materials for, *inter alia*, patches) but in view of the mentioning of overstitched nonwovens in LUCAST I, also on the teaching of KOKETSU (i.e., a document relating to increasing the strength of an article which is not a nonwoven, such as e.g., a safety belt) and additionally, on the teaching of WILDEMAN, i.e., a document which relates to stitch bonded fleece fabrics (i.e., not to nonwovens) which can be used for curtains, apparels, furnishing fabrics, fabrics for polyvinylchloride coated fabrics and electrode pockets in lead-acid storage batteries.

5. At pages 26 to 30 of the Examiner's Answer the Examiner repeatedly refers to inherent properties of a theoretical backing material which one of ordinary skill in the art would allegedly have provided on the basis of a combination of the teachings of the numerous

documents relied on by the Examiner. The Examiner also repeatedly alleges that “appellant has failed to show, or attempt [*sic*] to show, that the backing material taught by the applied prior art lacks the claimed property”. Appellants respectfully submit that they are not in a position to provide the showing requested by the Examiner because the Examiner has failed to identify a specific backing material which one of ordinary skill in the art would allegedly have provided.

6. Regarding the comments at page 31 of the Examiner’s Answer with respect to the rejection of claims 37-98 under the doctrine of obviousness-type double patenting over claims 1-27 of U.S. Patent No. 6,555,730 to Albrod et al. in view of MERKLE, Appellants refer to the comments under item 2. above and additionally submit that the mere fact that MERKLE discloses that the active substance dissolves in the hot melt adhesive and the adhesive can take up a large amount of active substance without loss of cohesiveness or adhesive strength clearly does not support the Examiner’s contention that “the active substance would not evaporate through and/or ooze out of the backing because the adhesive retains cohesiveness”. The reference to cohesiveness and adhesive strength in MERKLE apparently refers to the hot melt adhesive in the finished (cooled and solid) state, not to the hot melt adhesive in the hot (melted or liquid state), i.e., at the time when the hot melt adhesive having the active substance incorporated therein is applied onto the backing material.

Appellants further point out that the Examiner’s assertion at the bottom of page 31 of the Examiner’s Answer that “the active substance would not flow through the

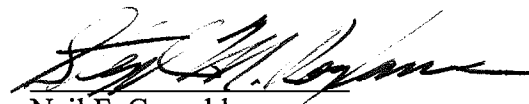
nonwoven backing layer because it is adhered to the protective layer” is apparently without merit as well. Firstly, it clearly is not the entire hot melt adhesive, let alone the entire active substance contained therein, that is adhered to the (optional) protective layer, but only the surface portion of the hot melt adhesive. Secondly, the protective layer would clearly be adhered to the hot melt adhesive only after the molten hot melt adhesive having the active substance incorporated therein has been applied to the backing layer.

CONCLUSION

The request to reverse the rejection of claims 37-98 and to return the application to the Examining Group for prompt allowance is respectfully maintained.

Although no fee is believed to be required for entry of this Reply Brief, the Patent and Trademark Office is hereby authorized to charge any fee that is deemed to be necessary to Deposit Account No. 19-0089.

Respectfully submitted,
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